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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,331	09/02/2004	Christopher Daly	COCH-0080-US1	8801

30678 7590 07/25/2007  
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EXAMINER
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PATTON, AMANDA K

ART UNIT	PAPER NUMBER
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3709

MAIL DATE	DELIVERY MODE
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07/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

#11

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/506,331	DALY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amanda Patton	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-31 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 32-34 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02 September 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group 1, claims 1-21, 32-34, and 38 in the reply filed on June 18, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: Page 20, line 28 is refers to figure 3-d, but mentions reference numbers only found in 3-c. Examiner suggests replacing "3-d" with "3-c". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "without there being any significant or indeed no change in the operation of the component" is indefinite because it is unclear whether any

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change in the operation of the component is acceptable or what “significant” change in operation consists.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-5, 10-14, 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Faltys et al. (US Pat 6,272,382, hereafter “Faltys ‘382”).

Regarding **claims 1 and 10**, Faltys ‘382 teaches an implantable component of a cochlear implant system, including (As shown in Figure 2C and Col. 12, lines 25-40):

- a housing for the stimulation unit that including collectively both ICS module 10, ISP module 30, lead 18 and jack 25;
- a coil 20 which act as a receiver antenna as part of a transcutaneous radio frequency link;
- an electrode assembly 12 adapted to apply electrical stimulation in accordance with the output of the stimulator unit;

wherein, following the implantation of the electrode assembly within the cochlea, a portion of the housing including ISP module 30, and thus the housing in general, can be

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moved from a first implanted position to at least one second implanted position without removal of the electrode assembly from the cochlea (as shown in Figure 3A).

Regarding **claims 4 and 5**, Faltys '382 additionally teaches two portions of the implantable device, ICS module 10 and ISP module 30, which are both substantially button-shaped, and thus the longitudinal axis can be drawn through both wherein the electrode assembly does not extend through the longitudinal axis and an upper and lower edge can be define such that the electrode assembly can be said to extend from the lower edge of the housing.

Regarding **claim 11**, Faltys '382 additionally teaches a device wherein the receiver coil 20 has a maximum thickness less than the maximum thickness of the ICS module portion of the housing (Figure 4C of the ICS module).

Regarding **claim 12**, Faltys '382 additionally teaches a receiver coil that is part of an RF link that allows both traditional transfer of data from the external headpiece coil and the implantable component 14 and back telemetry between the external headpiece coil 52 and the implantable component 14 (Col. 10, lines 20-27, and as shown through bidirectional arrows in Figure 1A-1E). The external component also contains an external receiver coil that is alignable with the position of the implantable receiver (as shown in Figure 1A, 2A, and described in Col. 8, lines 7-23).

Regarding **claim 13**, Faltys '382 also teaches an external unit containing receiver coil 52 that is capable of charging battery 34 (Col. 13, lines 53-57).

Regarding **claim 14**, Faltys '382 additionally teaches a device in which a magnet 87 can be inserted into the implantable device that serves to hold and align an external

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coil mounted to the outside of the head of the recipient with the receiver coil (Col. 17, lines 37-43).

Regarding **claim 16**, Faltys '382 additionally teaches a portion of the housing, namely lead 18, which is formed from a resiliently flexible material.

Regarding **claim 17**, Faltys '382 additionally teaches a region adjacent to one end of the upper or lower edges of the housing, namely lead 18, that is resiliently deformable, as to facilitate a change in the orientation of part of the housing, namely the ISP module, and thus the housing in general, in a surgical environment despite the electrode assembly remaining in its original implanted position.

Regarding **claim 18**, Faltys '382 teaches a method that includes the steps of (Col. 15, lines 42-60): accessing the site of implantation, repositioning the housing to remove and replace the ISP module, and closing the implantation site.

Regarding **claim 19**, as stated above, Faltys '382 additionally teaches all of the limitations of the implantable component as defined in claim 1.

Claims 2, 3 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Faltys et al. (US Pat. 6,308,101, hereafter "Faltys 101").

Regarding **claims 2 and 3**, Faltys '101 teaches a device comprising:

- a housing for a stimulator unit (subcutaneous device as shown in Figure 4A and 4B);
- a receiver antenna that is part of a transcutaneous radio frequency link (coil 172');

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- an electrode assembly that extends from the housing and is adapted to apply electrical stimulation in accordance with the output of the stimulator unit (electrode array cable 116);
- wherein the housing has a lateral axis (axis that runs along electrode array 116 and through the device).

Since electrode array 116 is inherently flexible (which it must be in order to be placed in the cochlea) the device of Figures 4A and 4B is capable of being rotated about a lateral axis without adjustment of the position of the implantation of the electrode assembly, as long as the adjustment leaves the proximal end of electrode array cable in the same place.

Regarding **claim 38**, Faltys '101 teaches a device comprising: an implantable stimulator unit ICS 112' as shown in Figures 1E; an external controller unit 138 which may include BTE 120 capable of being worn behind the ear; and a transmission system capable of transmitting signals from the external controller unit to the implantable stimulator unit (bidirectional arrows shown through skin of Figure 1E). This system is also inherently capable, using the symmetric implantable device as shown in Figures 4A and 4B, of being implanted in two different positions, one in which the transmission system is positioned distal from the external unit and one in which the transmission system is positioned proximal to the external controller. The device is capable of operating in both a magnet (when coupled to the external headpiece unit) and a magnetless (when using the fully implanted device only) mode.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under

35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Faltys '382 in view of Berrang et al. (US Pat. 6,648,914, hereafter "Berrang").

Regarding **claims 9 and 20**, Faltys '382 additionally teaches the implantation of the device behind the ear of the patient (Figure 3C), but does not specifically teach an implant that is removably implanted within a recess in the mastoid or the temporal bone of the recipient. It is well known in the art that the mastoid bone is part of the larger temporal bone. Berrang, however, teaches a device that is implanted in a recess in the outer plate of the skull behind the ear of the patient (Col. 13, lines 55-70). If it is to be placed in the position shown, the device inherently must be placed in a recess in the mastoid bone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the implant location of Berrang in the implantation of

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Faltys '382 in order to provide an implant location that would be the least intrusive and provide for the least complicated surgery possible.

Regarding **claims 15**, Faltys '382 does not teach a housing that is formed at least in part from a resilient flexible material. Berrang, however, teaches an implantable device in which part of the housing is constructed from a pliable bridge (Col. 3, lines 40-45). Neither Faltys '382 nor Berrang teach an implantable device in which the receiver coil is resiliently deformable relative to the housing. It would have been obvious, however, given that the housing of Berrang is made in part of a flexible material, to extend that flexible material portion into the part of the housing of containing the receiver coil in order to provide increased flexibility of the receiver coil. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the flexible implantable portion of the cochlear implant of Berrang to the implantable housing of Faltys '382 in order to provide a better way to fit the device against the curved skull.

**Claims 6-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys '382 as applied to claim 1 above, and further in view of Carter et al. (US Pat. 6,205,360, hereafter "Carter"). Faltys '382 does not teach an implantable component comprising a second electrode assembly. Carter, however, teaches a second extra-cochlear electrode assembly 13 (Figure 1 and Col. 6, lines 10-15). While neither Faltys '382 nor Carter explicitly teach a second electrode assembly extending from the housing in at least initially in an upward orientation from the upper edge of the housing, since the device of Faltys '382 is substantially button-shaped it would have been an obvious design choice to include the

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second electrode assembly such that it extended, at least initially, in an upward orientation from the upper edge of the housing. It would have been obvious to one of ordinary skill at the time the invention was made to include the second electrode assembly of Carter in the implantable component of Faltys '382 in order to provide a reference electrode for the monopolar stimulation.

**Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys '382 and Berrang as applied to claim 20 above, and further in view of Maniglia et al. (US Pat. 6,161,046, hereafter "Maniglia"). Neither Faltys '382 nor Berrang teach a method wherein the implantable component is held in place using one or more fastening devices to hold the component to the mastoid bone. Maniglia, however, teaches the use of tabs and screws 32 to subcutaneously mount battery 31 to the mastoid bone (Figures 2-3 and Col. 4, lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the method step of fastening the implantable component of Maniglia in the method steps of Faltys '382 and Berrang in order to provide a more secure way to hold the implantable device in place.

**Claims 32-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys '382 in view of Faltys '101. Faltys '382 does not teach a device in which the implantable component is implantable with either a first face of a second face adjacent or nearest the skin without there being any change in the operation of the component. Faltys '101, however, teaches an implantable device that, as disclosed in Figures 4A and 4B, is symmetrical about its faces and thus there will be no change in operation if it is implanted

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with one or the other faces nearest to the skin. The device is substantially symmetrical about two different planes and these two planes can be labeled the longitudinal and the lateral planes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the ability to be implanted with either face adjacent or nearest to the skin of Faltys '101 in the implantable component of Faltys '382 in order to provide a device with the ability to be implanted in a greater variety of positions than originally capable.

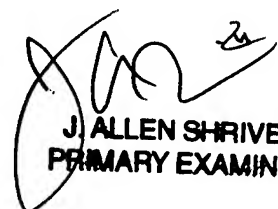
### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Thursday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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7/17/2007

  
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PRIMARY EXAMINER